

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



APPLICANTS :	Miller, T.A.	CONFIRMATION NUMBER :	8627
SERIAL NUMBER :	10/600,132 (Now U.S. Patent No. 7,456,219)	EXAMINER :	Valenrod, Y.
FILING DATE :	June 19, 2003	ART UNIT :	1621
FOR :	Polymorphs of Suberoylanilide Hydroxamic Acid		

MAIL STOP PATENT EXT.

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. §1.705(d)

Sir:

This Application is submitted in response to the Decision on Request for Reconsideration of Patent Term Adjustment and Notice of Intent to Issue Certificate of Correction (herein the "Decision"), mailed on July 28, 2009.

The above-identified application issued as U.S. Patent No. 7,456,219 on November 25, 2008. The total patent term adjustment calculated by the USPTO for this application was 795 days. The USPTO arrived at this PTA by calculating 821 days under 37 C.F.R. §1.702(a)(1), (2), and (4), plus 890 days under 37 C.F.R. §1.702(b) (See, e.g., pages 6-7 of the Decision, particularly Footnote 5). The USPTO then determined that all 890 days under the 37 C.F.R. §1.702(b) period overlapped with the 821 days under the 37 C.F.R. §1.702(a) period, but did not add the §1.702(a) and §1.702(b) periods together. Rather, the USPTO took the 890 days under the §1.702(b) period as the maximum USPTO delay and then subtracted the period of applicant delay (the USPTO calculated applicant delay as 95 days), thereby arriving at 795 days.

This Application seeks to correct two errors. First, the period of applicant delay should have been calculated as 74 days, not 95 days -- the USPTO's 21 day "deduction" for the September 18, 2008 IDS was not proper (as detailed herein). Second, because the §1.702(a) and §1.702(b) periods do not overlap, contrary to what was stated in the Decision, the USPTO should add the entire §1.702(a) period during which the application was pending, less any USPTO delay occurring after June 15, 2006 (which was 3 years from the date the application was filed), plus

the period under §1.702(b) attributed to the failure of the USPTO to issue the patent within 3 years after the date on which the application was filed. Thus, the correct PTA under §1.702(a) is 821 days, less the 143 days and 26 days of USPTO delay that occurred after June 16, 2006, or 652 days. From 652 days, 74 days attributed to applicant delay should be subtracted, resulting in 578 days under §1.702(a). Applicants contend that the USPTO should add the §1.702(a) and §1.702(b) periods together to a total USPTO delay of 1468 days. Applicants hereby respectfully request reconsideration of the patent term adjustment for this application.

Applicants thank the Office of Petitions for withdrawing the 604 days previously attributed to the period of adjustment, as well as the 48 days relating to the submission of the "Miscellaneous Letter" filed on August 1, 2008, which was formerly attributed to Applicant delay.

In support of this request, Applicants submit the following statement of facts pursuant to 37 C.F.R. § 1.705(b).

(i) The patent term adjustment calculated by the USPTO under 37 C.F.R. § 1.702(a)(1), (2), and (4) is 821 days, taking into consideration the Restriction Requirement mailed by the USPTO on June 2, 2006, i.e., 14 months and 652 days after the application was filed on June 19, 2003, in addition to the Office's failure to respond to the reply of July 16, 2007 until December 12, 2007, 4 months and 26 days after the date on which the reply was filed, as well as four months and 143 days attributed to the issuance of the patent on November 25, 2008 after payment of the issue fee by Applicants on March 5, 2008. See, for example, pages 6-7 of the Decision, particularly Footnote 5.

(ii) The 821 days attributed to USPTO delay should be reduced by the number of days attributable to USPTO delay occurring after June 16, 2006 (three years from the date the application was filed), i.e., 821 days - 26 days - 143 days, or a total of 652 days. Thus, the correct patent term adjustment under 37 C.F.R. §1.702(a) is 652 days.

(iii) In response to Applicants' request for review of the patent term calculation under § 1.702(b) as filed on December 16, 2008, the Office determined that the correct term was 890 days, reduced by 95 days allegedly attributed to Applicant delay, resulting in

795 days attributed to the period of adjustment, as set forth in the Decision of July 28, 2009.

(iv) The correct patent term adjustment calculated under 37 C.F.R. § 1.702(b) is 890 days, due to the failure of the Office to issue a patent within three years after the date on which the application was filed. This application was filed on June 19, 2003. Accordingly, the application should have issued three years later, on June 19, 2006. However, the actual issue date was November 25, 2008, which is a delay of 890 days.

(v) The Office has maintained the reduction of 21 days of delay allegedly attributed to Applicants under 37 C.F.R. § 1.704 for the filing of an Information Disclosure Statement (“IDS”) on September 18, 2008. The Decision of July 28, 2009 states that the IDS filed on September 18, 2008 did not include the proper statement under 37 C.F.R. § 1.704(d) and upheld the 21 day reduction for this reason. Applicants believe that the 21 day reduction should be withdrawn, because the September 18, 2008 IDS was filed within 30 days of the receipt of the information in the IDS from a foreign patent office. See, e.g., Exhibit A submitted in the Application filed on December 16, 2008. Whether the IDS statement of September 18, 2008 was in proper form is purely a matter of procedure. What is undisputed here is that the IDS was, in fact, filed within 30 days of receipt of the information in the IDS from a foreign patent office and the factual circumstances of the IDS filing within the 30 day time period alone warrants withdrawal of the 21 day reduction, despite the absence of the exact, specific language of 37 C.F.R. 1.704(d) in the IDS statement of September 18, 2008. Applicants respectfully request withdrawal of the 21 day reduction in patent term adjustment erroneously attributed to Applicant delay.

(vi) Therefore, in view of the foregoing, adjustment sought under 37 C.F.R. § 1.703(f) is the sum of the periods under § 1.702(a)(652 days) and § 1.702(b)(890 days), less the delays attributable to Applicant (74 days). Accordingly, Applicants respectfully request an adjustment of patent term under § 1.703(f) to indicate a total PTA of 1,468 days in view of the arguments presented herein.

In response to Applicants' request for the adjustment under § 1.703(f) to include the sum of the periods under §1.702(a) and §1.702(b) under the decision of *Wyeth v. Dudas*, 580 F.Supp.2d 138 (D.C. Circuit, 2008), rather than the greater of these two periods, the Decision contends that Applicants' interpretation of the period of overlap is inconsistent with the USPTO's interpretation of the overlap provision.

The USPTO has interpreted 35 U.S.C. §154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. §154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. §154(b)(1)(B), but not as permitting patent term adjustment under both. In other words, the Decision contends that "any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment, citing the *Changes to Implement Patent Term Adjustment Under Twenty Year Term, Final Rule*, 65 Fed. Reg. 54366 (September 18, 2000). The Decision takes the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. §154(b)(1)(B), the entire period during which the application was pending before the USPTO (except for periods excluded under 35 U.S.C. §154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. §154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. §154(b)(2)(A).

In the instant case, under 35 U.S.C. §154(b)(1)(A) and 37 C.F.R. §1.702(a)(1), (2), and (4), 821 days of patent term adjustment were accorded during the pendency of the application for USPTO delay prior to the issuance of the patent. Pursuant to 35 U.S.C. §154(b)(1)(B) and 37 C.F.R. §1.702(b), 890 days of patent term adjustment accrued for USPTO issuance of the patent more than 3 years after the filing date of the application. The Decision contends that entry of both the 890 days and the 821 days is neither permitted nor warranted, and granted Applicants a revised determination of patent term adjustment at the time of the issuance of the patent to be 795 days (890 days of USPTO delay, less 95 days allegedly attributed to Applicant delay).

Applicants respectfully disagree with the Decision's interpretation of the three-year pendency provision of 35 U.S.C. §154(b)(1)(B) in view of *Wyeth*. Notwithstanding the

interpretation set forth in the Decision, Applicants reiterate that, applying the rule in *Wyeth* to the present facts, the period for “A” delays ends on June 19, 2006, which is three years from the filing date of this application, June 19, 2003. The period for “B” delay begins on June 20, 2006 and ends on the date of issuance of the patent, November 25, 2008, a period of 890 days. Applicants maintain that the correct calculation under *Wyeth*, where the court expressly rejected the USPTO’s view that any administrative delay under 35 U.S.C. § 154(b)(1)(A) (“A delays”) overlaps with any 3-year maximum pendency delay under 35 U.S.C. § 154(b)(1)(B) (“B delay”). In the district court’s view, the only A delays which overlap with the B delay are those which occur after the B period begins, which is when the Patent Office has failed to issue a patent within three years of an application’s filing date, and not before. *Wyeth*, 580 F.Supp.2d at 141-142. Applicants note that the USPTO’s calculation of 821 days under 37 C.F.R. § 1.702(a) overlaps by 169 days (143 days + 26 days), which are attributed to USPTO delay that occurred after June 16, 2006, and have subtracted these 169 days from the A period accordingly, resulting in a total A period of 652 days.

Accordingly, the total patent term adjustment should be calculated from the sum of the non-overlapping A and B periods (652 + 890 days), less the delays due to applicant during the B period, i.e., 74 days (95 days allegedly attributed to Applicant delay, less the 21 days relating to the September 18, 2008 and erroneously attributed to Applicant delay), resulting in a total patent term adjustment of 1,468 days. Applicants note that *Wyeth* is currently on appeal at the Federal Circuit. Therefore, Applicants respectfully request that the USPTO hold its decision regarding the three-year provision in abeyance until the Federal Circuit has rendered its decision.

Applicant notes that the above-identified application is not subject to a terminal disclaimer.

In summary, Applicant respectfully requests an adjustment of patent term under 37 C.F.R. § 1.703(f) to indicate a total PTA of 1,468 days.

Pursuant to 37 C.F.R. § 1.705(d) and § 1.18(e), the fee required for filing this application for patent term adjustment is \$200.00. Enclosed is Check No.5063 in the amount of \$200.00 as required under § 1.18(e).

Express Mail Label No.: EM 360782798US
Date of Deposit: August 28, 2009

Attorney Docket No. 24852-201002US
(Formerly 24852-501 CIP)

No additional fees are believed to be due; however, the Commissioner is authorized to charge such fee, or credit any overpayment in fees to Deposit Account No. **50-0311**, Customer Number **35437**, Attorney Docket No. **24852-201002US**.

Respectfully submitted,

Dated: August 28, 2009

Michelle A. Iwamoto
Ivor R. Elrifi, Reg. No. 39,529
Michelle A. Iwamoto, Reg. No. 55,296
Attorneys/Agents for Applicants
c/o MINTZ, LEVIN, *et al.*
666 Third Avenue-24th Floor
New York, New York 10017
Telephone: (212) 935-3000
Telefax: (212) 983-3115
Tel: (212) 692-6296
Fax: (212) 983-3115

4702595v.1